FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MEDEVA PHARMA SUISSE A.G., WARNER CHILCOTT PHARMACEUTICALS INC., and WARNER CHILCOTT COMPANY, LLC, Plaintiffs, vs. PAR PHARMACEUTICAL, INC., and EMET PHARMACEUTICALS, LLC, Defendants.	Civil Action No. 10-4008 (FLW) **OPINION**

WOLFSON, United States District Judge:

Presently before the Court is a motion by Plaintiffs Medeva Pharma Suisse A.G., Warner Chilcott Pharmaceuticals Inc., and Warner Chilcott Company, LLC (collectively referred to as "Plaintiffs") to dismiss Defendants Par Pharmaceutical, Inc.'s and Emet Pharmaceuticals, LLC's (collectively referred to as "Defendants'") counterclaim for declaratory judgment regarding the validity of Plaintiffs' United States Patent #5,541,171 ("'171 Patent"). Plaintiffs move to dismiss the counterclaim, pursuant to Fed. R. Civ. P. 12(b)(1), on the ground that Defendants lack standing to bring the counterclaim based upon Plaintiff's offering of a covenant not to sue Defendants on the '171 Patent. For the reasons that follow, the Court finds that Defendants lack standing to seek declaratory judgment with regard to the '171 Patent. Accordingly, Plaintiff's motion is granted, and Defendants' counterclaim for declaratory judgment under the '171 Patent is dismissed.

I. Background

Plaintiffs are makers of the brand name drug Asacol®, which is a drug approved by the Food and Drug Administration ("FDA") and listed under NDA No. 19-651 in the Orange Book.[1] Answer, ¶ 19. Plaintiffs are also owners of the '171 Patent and another related patent, United States Patent #5,541,170 ("'170 Patent"), which are both listed in the Orange Book in association with Asacol®. Counterclaim, ¶ 13. In October 2007, Roxane Laboratories, Inc. ("Roxane") filed an Abbreviated New Drug Application ("ANDA") requesting approval to market generic versions of Asacol®, which prompted Plaintiffs to first file an infringement action against Roxane in a separate suit pending before this Court. Counterclaim, ¶ 22. Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (the "Act"), a generic drug company like Roxane may submit an ANDA as part of a streamlined FDA approval process for the generic drug.[2]

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[1] Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (the "Act"), to govern the FDA's approval process for new and generic drugs. Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008). As the Federal Circuit in Caraco explains, a pioneering drug company must submit a New Drug Application ("NDA") to the FDA for approval in order to introduce a new drug into the market. Id. As part of that process, the pioneering drug company must also inform the FDA of all patents associated with the new drug or the methods of using the new drug. Id. Once approved, the FDA lists the NDA as well as all the associated patents in the "Orange Book." Id. The "Orange Book" is the commonly-known name of a FDA publication titled "Approved Drug Products With Therapeutic Equivalence Evaluations." FDA lists all approved NDAs, and their associated patents, in this publication. Id. The Court will refer, generally, to a new drug that has been approved by the FDA and listed in the Orange Book as a "brand-name drug" throughout this Opinion.

[2] The Act also governs the approval process for generic drugs. Any generic drug company desiring to make generic copy of a brand-name drug may submit an ANDA. Caraco, 527 F.3d at 1282. An ANDA streamlines the approval process for generic drugs by allowing the applicant to rely on the safety and efficacy studies of the brand-name drug, if the applicant can provide information to show that its generic drug and the brand-name drug share the same active ingredients and are bioequivalent. Id. The Act provides for several different processes to obtain

After the suit against Roxane was filed, on or before June 22, 2010, Defendants filed their own ANDA with the FDA, seeking approval to market their generic versions of Asacol®. Answer, ¶ 22. Upon notice of Defendants' ANDA application, Plaintiff filed the instant action on August 5, 2010, alleging that the ANDA infringed upon the '170 Patent. Noticeably, Plaintiffs made no claim that Defendants' ANDA infringed upon the '171 Patent.

To counter, Defendants filed CAPC counterclaims under 35 U.S.C. § 271(e)(5) for declaratory judgment of non-infringement or invalidity with respect to both the '170 Patent and the '171 Patent, in order to resolve all patent-related uncertainties related to their ANDA in the same lawsuit.[3] In response, Plaintiffs offered Defendants a covenant-not-to-sue, presently or in the future, for the '171 Patent. Plaintiffs claim that the Covenant resolves all uncertainties with regard to the '171 Patent, and now move to dismiss Defendants' counterclaim for the '171 Patent, contending that the Covenant deprives Defendants of standing. In Plaintiff's view, the Covenant effectively redresses all injuries Defendants may suffer with respect to the '171 Patent. Defendants oppose the motion, asserting that there is standing because the Covenant does not address all of Defendants' potential injuries arising out of the '171 Patent.

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approval of an ANDA. If a generic company wants to obtain approval of a generic drug before all the patents associated with the brand-name drug have expired, by claiming that either the patents are invalid or that the ANDA will not infringe upon any of the patents, then it must file what is known as a Paragraph IV ANDA. Id. at 1282-83.

[3] To facilitate the early resolution of patent disputes between a Paragraph IV applicant and the patent holders of the brand-name drug, the Act expressly provides that the mere filing of a Paragraph IV ANDA constitutes an act of patent infringement. Id. at 1283. To further facilitate the early resolution of patent disputes, the Act also provides that the ANDA applicant may also seek declaratory judgments as to the invalidity/non-infringement of the patents associated with the brand-name drug, in the event the patent holder does not bring an infringement challenge. Caraco, 527 F.3d at 1285.

II. Standard of Review

A party may move for dismissal pursuant to Fed. R. Civ. P. 12(b)(1) based on lack of subject matter jurisdiction. A challenge to a plaintiff's standing is a challenge to subject matter jurisdiction. Pa. Prison Soc'y v. Cortes, 622 F.3d 215, 229 (3d Cir. 2010). Under Article III of the Constitution, because courts may only adjudicate "cases and controversies," a party must have standing to bring a claim in court. To establish standing, a party must show that 1) he suffered some actual or threatened injury as a result of illegal conduct by the defendant; 2) the injury can be fairly traced to the challenged action; and 3) the injury is likely to be redressed by a favorable decision. Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., 528 U.S. 167, 180-81 (2000).

When faced with a Rule 12(b)(1) challenge to jurisdiction, the court "must start by determining whether [it is] dealing with a facial or factual attack to jurisdiction. If [it] is a facial attack, the court looks only at the allegations in the pleadings and does so in the light most favorable to the plaintiff." U.S. ex rel. Atkinson v. PA. Shipbuilding Co., 473 F.3d 506, 514 (3d Cir. 2007). "If [it] is a factual attack, however, it is permissible for a court to review evidence outside the pleadings." Id. "[T]he trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." Mortensen v. First Federal Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977). A jurisdictional challenge is a factual challenge if "it concerns not an alleged pleading deficiency, but rather the actual failure of [plaintiff's] claims to comport with the jurisdictional prerequisites." U.S. ex rel. Atkinson, 473 F.3d at 514.

In the instant matter, Plaintiffs make a factual challenge to jurisdiction, arguing that Defendants lack injury-in-fact to seek a declaratory judgment under the '171 Patent. As such, the Court will consider all relevant evidence in determining its authority to hear the case.

III. Discussion

Defendants bring their counterclaims pursuant to the Declaratory Judgment Act, which provides that: "[i]n a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration ...." 28 U.S.C. § 2201(a). Despite the "virtually unflagging obligation of the federal courts to exercise the jurisdiction given them," Colo. River Water Conservation Dist. v. United States, 424 U.S. 800, 817 (1976), the discretionary language of the Declaratory Judgment Act means federal courts have "no compulsion to exercise [the] jurisdiction" the statute grants. Brillhart v. Excess Ins. Co. of Am., 316 U.S. 491, 494 (1942). In other words, the statute "confers a discretion on the courts rather than an absolute right upon the litigant." Wilton v. Seven Falls Co., 515 U.S. 277, 287 (1995). Thus, "[i]n the declaratory judgment context, the normal principle that federal courts should adjudicate claims within their jurisdiction yields to considerations of practicality and wise judicial administration." Id. at 288.

According to the U.S. Supreme Court, the proper standard for ascertaining whether a declaratory judgment action satisfies Article III's standing requirement is

> whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007). Of course, the touchstone of the standing analysis is that there is an actual or immenent concrete injury-in-fact traceable to the complained-of-conduct, and there must be "a likelihood that the requested relief will redress the alleged injury." Caraco, 527 F.3d at 1291 (quoting Steel Co. v. Citizens for a Better Env't, 523 U.S.

83, 102-03 (1998)). In the patent context, the alleged injury is typically "a restraint on the free exploitation of non-infringing goods." Id. (quotation marks and citation omitted).

Because Plaintiff's challenge to Defendants' Article III standing relates to the FDA approval process for generic drugs, the Court must briefly explain the inner workings of the Hatch-Waxman Act. The Act encourages entry into the market by generic drug companies that believe the patents associated with a brand-name drug they seek to replicate are either invalid or that its generic drugs would not infringe those patents. The Act provides that the first filer of a Paragraph IV ANDA against a brand-name drug (the "First Filer"), who often bears the brunt of the litigation costs of any subsequent infringement challenge, is entitled to a 180-day generic market exclusivity period. Caraco, 527 F.3d at 1283. Until this period expires, the FDA may not approve any later-filed Paragraph IV ANDAs for the same brand-name drug. Id. Most importantly, to be entitled to this market exclusivity period, the First Filer need not establish that the patents associated with the brand-name drug are invalid or that its ANDA does not infringe them; all the Act requires is the filing of a substantially-completed Paragraph IV ANDA. Id.

As initially enacted, the Act provided that the 180-day market exclusivity period it creates for First Filers does not begin to run until either one of two triggers occurs: 1) the commercial-market trigger, which occurs when the First Filer first begins to market its generic drug, or 2) the court-judgment trigger, which occurs on the date of a final court decision finding that all of the associated patents of a brand-name drug are either invalid or not infringed. Id. (The Act was amended in 2003, as discussed *infra*.) Only the First Filer can trigger the commercial-market trigger, but any subsequent ANDA filer may trigger the court-judgment trigger. Because the FDA cannot approve any subsequent ANDA until the marketing exclusivity period expires, a subsequent ANDA

filer has a strong incentive to trigger the running of the exclusivity period, by using the court-judgment trigger, to allow early approval of its own application. Id. at 1284. Conversely, the maker of the brand-name drug has a strong incentive to prevent a triggering event, in order to forestall potential competitors from entering the market. Id.

In their effort to prevent a triggering event, some brand-name drug companies developed strategies that exploited the loopholes under the initial version of the Act. One such strategy was the use of covenants-not-to-sue. See Id. at 1288-89. In such a scenario, the brand-name drug company brings a patent-infringement suit against a Paragraph IV ANDA filer only on some, but not all, of the patents associated with the brand-name drug, and then offers the ANDA filer a covenant-not-to-sue on the other patents. Id. at 1288. As explained by the court in Caraco, this strategy was developed in part due to the prevailing case law in the Federal Circuit at the time, which applied a two-part reasonable-apprehension-of-suit test to determine standing for CAPC actions.[4] Id. The rationale behind this strategy was that without a threat of present or future litigation on those other patents, there would be no reasonable apprehension of an infringement suit. Therefore, under that rationale, the ANDA filer would lack standing to file a declaratory judgment. See, e.g., id. at 1289; Janssen Pharm. N.V. v. Apotex, Inc., 540 F.3d 1353, 1359-60 (Fed. Cir. 2008). Lacking standing, the ANDA filer would not be able to obtain a court decision that declares all of the patents associated

[4] The reasonable-apprehension-of-imminent suit test stated that, to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity, there must be both "(1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity." Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1332 (Fed. Cir. 2005) abrogated by MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).

with the brand-name drug as either invalid or not infringed upon, and consequently, the ANDA filer would be unable to trigger the market exclusivity period. See Caraco, 527 F.3d at 1289-90.

Another tactic involved what amounts to collusion between the brand-name drug company and the First Filer. In this scenario, the First Filer would enter into agreement with the brand-name drug company not to market its generic drug until after all patents associated with the brand-name drug have expired. Id. This tactic had the effect of preventing the FDA from ever approving any subsequent ANDAs until the patent expired. See 149 Cong. Rec. S15884 (Nov. 25, 2003) (remarks of Sen. Kennedy). Indeed, this tactic, when combined with the selective covenants-not-to-sue, prevented entry of any generic drug company into the market until all the patents expired.

It is against this backdrop of legal tactics and collusion that the Federal Circuit held in Caraco that a subsequent ANDA filer has justiciable injury and standing to challenge, and therefore can seek declaratory judgment against all patents associated with that brand name drug, if 1) the subsequent ANDA filer is prevented from entering the market by the market exclusivity period, and 2) a court decision would invoke the court-judgment trigger to remove that exclusivity.[5] Caraco, 527 F.3d at 1297. In so holding, the Caraco court recognized the potential indefiniteness of the market exclusivity period, and the requirement that under the Act, a court decision must cover all patents associated with a brand-name drug in order to invoke the court-judgment trigger. Id. at 1291-93. The Federal Circuit reaffirmed its Caraco decision in Janssen, ruling that a subsequent ANDA filer did not have standing to seek declaratory judgments after it stipulated to the validity of one of the

[5] Although Caraco was decided in 2008, it applied the pre-2003 version of the Act because the ANDAs involved in that case were filed prior to the Act's 2003 amendment. 527 F.3d at 1283 n.2.

patents associated with the brand-name drug. Janssen, 540 F.3d at 1361.[6]

In 2003, Congress, recognizing the problems associated with the market exclusivity period and the use of the court-judgment trigger, amended the Act to provide a comprehensive system of forfeiture in which a First Filer would lose its market exclusivity if it does not exercise that right. See, e.g., 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa)(AA) (providing that the First Filer forfeits its right to exclusivity if it fails to market its drug 75 days after the approval of its application); 21 U.S.C. § 355(j)(5)(D)(i)(IV) (providing that the First Filer forfeits its right to exclusivity if it fails to obtain approval of its application within 30 months of filing). Congress also retained the court-judgment trigger. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb); 149 Cong. Rec. S15885; Caraco, 527 F.3d at 1294 n.13. However, the amendment did not specifically address the patent-holder practice of offering a covenant-not-to-sue on one of its patents and, thereby, depriving a subsequent filer of standing.

Plaintiffs argue that the 2003 amendment calls into question the continued viability of Caraco. Because the 2003 amendment removed any potential indefiniteness of the market exclusivity period, Plaintiffs contend that Defendants no longer suffer any injury that needs to be redressed by the Court. Conversely, Defendants advocate that the Court continue to adhere to Caraco's holdings, i.e. that as long as they are barred from entering the market by the First Filer's market exclusivity period and the Court is able to trigger a forfeiture of that exclusivity, Defendants have standing to seek declaratory judgment on the '171 Patent. Indeed, the Federal Circuit's

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[6] While Jassen also involved a covenant-not-to-sue, the Janssen court did not rely on the covenant for its decision. Instead, it held that the subsequent ANDA filer's prior stipulation as to the validity, infringement, and enforceability of another patent associated with the brand-name drug deprived it of standing to sue under all other patents. Id. In effect, that filer's stipulation prevented the court from issuing a decision capable of invoking the court-judgment trigger under the Act, and hence rendered the court unable to redress its injuries. Id. at 1362.

decision in Teva Pharmaceuticals USA, Inc. v. EISAI Co., Ltd., 620 F.3d 1341 (Fed. Cir. 2010), supports this view (holding that assertions that First Filer delayed in obtaining FDA approval and, consequentially, delayed triggering 180-day exclusivity period, sufficiently alleges standing on behalf of ANDA applicant).

While both parties make compelling arguments in support of their positions, the Court need not rule on this issue because the Court finds that Roxane, the First Filer here, appears to have forfeited its market exclusivity on account of its failure to obtain tentative approval of its ANDA within 30 months of filing its application for approval.[7] Under the Act, as amended in 2003, the First Filer forfeits its market exclusivity if:

> [t]he first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

21 U.S.C. § 355(j)(5)(D)(i)(IV). Cf. Teva Pharmaceuticals USA, Inc. v. Sebelius, 595 F.3d 1303, 1310 (D.C. Cir. 2010) (acknowledging that failure to obtain tentative approval results in forfeiture under the Act); Hi-Tech Pharmacal Co., Inc. v. U.S. Food and Drug Admin., 587 F.Supp.2d 1, 5 (D.D.C. 2008) (noting that "[t]he FDA asserts that its general practice is to decide issues of exclusivity and forfeiture only when an ANDA is ready for final approval, and that it does so "because [there are] many factors that may influence eligibility for exclusivity up to the time an application is ready for approval (e.g., patent expiration, patent delisting, *failure to obtain tentative approval within 30 months*, withdrawal of ANDA) and could thus render a premature eligibility

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[7] To be clear, the failure-to-obtain-tentative approval forfeiture event differs from the failure-to-market forfeiture event. The former is found in subsection 355(j)(5)(D)(i)(IV) of the Act, while the latter is found in subsection 355(j)(5)(D)(i)(I). Moreover, the latter appears to apply only to those ANDA applicants that have already obtained tentative approval.

determination incorrect.") (emphasis added). Here, Roxane filed its ANDA in October 2007. Thus, its thirty-month period to obtain tentative approval, according to Defendants' allegations, appears to have expired in April 2010. That there has not been a formal determination that Roxane forfeited its exclusivity period, by either a court or the FDA, does not alter may analysis. In making a conclusion as to standing, I must rely upon Defendants' allegations in the counterclaim, which allegations indicate that First Filer Roxane forfeited its exclusivity.

Seizing on the Act's language exempting a failure to obtain tentative approval "caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed," 21 U.S.C. § 355(j)(5)(D)(i)(IV), Defendants argue that its allegations do not suggest that Roxane forfeited its eligibility because, in August 2010, the FDA announced a change to the bioequivalence requirements for a class of drugs covering Roxane's application. The flaw in Defendant's argument is that this alleged announcement came four months after Defendants allege that Roxane's 30-month tentative approval period had expired and, therefore, could not have been the cause of Roxane's failure to obtain approval. Moreover, nothing in the record suggests that an approval or extension of Roxane's application from the FDA is imminent; in fact, at this juncture, more than 10 months after Roxane's 30-month approval allotment has expired, the Court cannot discern whether an approval or extension will ever be granted. Therefore, based on the allegations in Defendants' counterclaim, and the plain language of the Act, Defendants have not sufficiently alleged that they are barred from entry into the market. This means that any potential barrier that could result from a subsequent approval and reinstatement of Roxane's market exclusivity is speculative at best, and does not meet the Article III requirement of actual or imminent injury for standing. Laidlaw, 528 U.S. at 180.

Because the 180-day exclusivity period is no longer in effect, according to Defendants' allegations, the only remaining cognizable injury is a threat of suit on the '171 patent. Post-Caraco, the Federal Circuit has held that a covenant-not-to-sue will deprive a subsequent ANDA applicant of standing. See Dow Jones & Co., Inc. v. Ablaise Ltd., 606 F.3d 1338, 1348 (Fed. Cir. 2010) ("In the case at bar, [the] covenant not to sue avowed that [the patent holder] would not sue . . . for any acts of infringement of its . . . patent. The covenant therefore extinguished any current or future case or controversy between the parties, and divested the district court of subject matter jurisdiction."). Compare Teva Pharmaceuticals USA, Inc. v. EISAI Co., Ltd., 620 F.3d 1341 (Fed Cir. 2010) (holding that, where First Filer's exclusivity period has not been forfeited, that covenant-not-to-sue would not deprive the subsequent ANDA of standing).

Here, Plaintiffs offered Defendants a Covenant stating, in pertinent part, that it:

> covenant[s] not to sue [Defendants] under any patent claim of United States Patent 5,541,171 ("the '171 Patent") only with respect to:
>
> 1. the filing with the United States Food and Drug Administration of Abbreviated New Drug Application ("ANDA") NO. 200-730 as it existed on the date of execution of this Covenant, which seeks approval to engage in the commercial manufacture, use, and sale of a delayed release dosage form containing 5-amino-salicylic acid; and/or
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> 2. the manufacture, use, and sale [sic] offer for sale, or importation by or for [Defendants] of the drug product or formulation of any dosage strength described in ANDA No. 200-730 as it existed on the date of execution of this Covenant, if approved by the United States Food and Drug Administration.
>
> [Plaintiffs] further covenant not to assert the '171 Patent against any [Defendant] parent, subsidiary, affiliate, customer, manufacturing partner, supply partner, marketing partner, licensee, or purchaser of the portion of [Defendant's] business to which ANDA No. 200-730 relates, based on any activity described in paragraph 2 above.

Ainsworth Decl, Exh. A. Defendants have not argued, nor does the Court perceive, that this language does not sufficiently evidence Plaintiff's commitment not to sue, or that it is too limited in breadth or scope. Thus, in light of the Covenant offered by Plaintiffs, the Court finds that Defendants suffer no justiciable injury redressible by the Court with respect to the '171 Patent, and thus have no standing to seek a declaratory judgment on that Patent.

IV. Conclusion

For the foregoing reasons, Plaintiffs' motion is **GRANTED**, and Defendants' counterclaim with respect to the '171 Patent is **DISMISSED**. An appropriate Order shall follow.

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge

Date: March 28, 2011